

The logo features a stylized 'H' formed by two white curved lines. The top and bottom curves are solid, while the vertical stems are composed of a series of small white dots.

HArmonyCa<sup>®</sup>

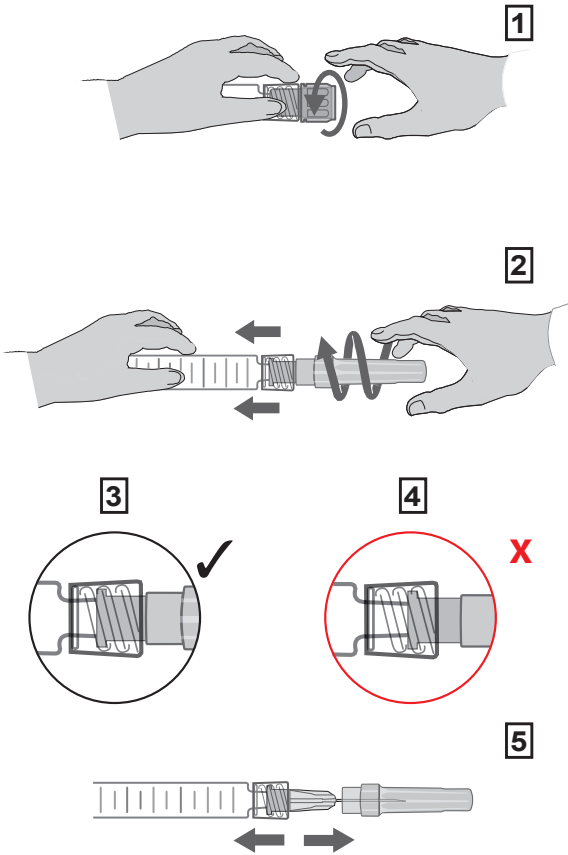
Lidocaine

# Instructions *for Use*

This document contains:

- 1 Directions for Use
- 2 Patient Implant Cards

FIGURE 1



**PRESCRIPTION ONLY MEDICINE**

**KEEP OUT OF REACH OF CHILDREN**

*This medical device contains 3mg/ml lidocaine hydrochloride, 20mg/ml sodium hyaluronate and calcium hydroxyapatite microspheres of 25-45 microns diameter.*

## HARMONYCA<sup>®</sup> LIDOCAINE - INJECTABLE FACIAL IMPLANT

**Read these INSTRUCTIONS FOR USE carefully and in their entirety before using the device.**

This document is intended to guide the healthcare professional in the use of this product. It is not intended to serve as a reference for surgical techniques.

Refer to the instructions, contraindications and warnings prior to use.

### DESCRIPTION

HArmonyCa<sup>®</sup> Lidocaine is a sterile, apyrogenic, viscous, opaque, injectable, semi-solid, latex free and bio-degradable dermal implant. It consists of synthetic calcium hydroxyapatite microspheres, formulated to a concentration of 55.7%, suspended in a cross-linked sodium hyaluronate gel from a non-animal source and is provided in a 1.25 mL prefilled graduated, glass syringe. The implant is intended for sub-dermal and deep dermal use in specific facial regions. The product contains 0.3% (w/v) lidocaine HCl to reduce pain during treatment.

### PACKAGE CONTENT

2 pre-filled syringes, 1.25 mL each.

2 single-use 27G 1/2" thin-wall sterile needles.

### COMPOSITION

Calcium hydroxyapatite microspheres of 25-45 microns diameter (55.7%), Cross-linked sodium hyaluronate gel (20mg/ml), Phosphate buffer, Lidocaine hydrochloride (3mg/ml).

### INDICATIONS

HArmonyCa<sup>®</sup> Lidocaine is a dermal filler intended for facial soft tissue augmentation and should be injected into the deep dermal and sub-dermal layers. The lidocaine in the product is for reducing pain during treatment.

See CONTRAINDICATIONS for excluded facial regions.

### CONTRAINDICATIONS

HArmonyCa<sup>®</sup> Lidocaine is contraindicated:

- in patients with a known sensitivity to any of the product components.
- in patients suffering from skin disease or abnormal skin conditions.
- in patients suffering from an infection or inflammation (either acute or chronic) at or near the treatment site.
- in patients susceptible to keloid formation, hypertrophic scarring or developing inflammatory skin conditions.
- in patients with impaired wound healing due to systemic disorders, medicinal drugs or unhealthy or poorly-vascularised tissue.
- in patients suffering from prolonged bleeding or tissue healing due to medical conditions or medicinal drugs.
- in patients with a history of anaphylactic reactions and/or multiple severe allergies.
- in patients with a known sensitivity to steroids or who are contraindicated to be treated with steroids.

## Instructions *for Use*

- for injection into the glabellar or periocular areas.
- for injection into the lips and perioral region.
- for injection into regions containing foreign bodies.
- in patients presenting with herpes.
- in patients with autoimmune diseases.
- for injection into blood vessels and to highly vascularised areas.
- for injection into the epidermis or superficial dermis.
- in breastfeeding or pregnant women.
- in patients below the age of 18.
- in patients with known hypersensitivity to lidocaine or to other amide-type local anaesthetics.
- in patients with conditions for which lidocaine is contraindicated.

### WARNINGS

- HArmonyCa® Lidocaine must not be injected into blood vessels. It is advised to aspirate before injecting the implant. Introduction into blood vessels can result in vascular occlusion, ischaemia, infarction and necrosis of local or distant tissues.
- HArmonyCa® Lidocaine must not be used in sites presenting an inflammatory reaction, infection or tumour. Defer treatment until the reaction clears or condition is controlled.
- The safety and efficacy of the product has not been evaluated in patients with a history of keloid formation, connective tissue disease, active bleeding disorders, active hepatitis, clinically significant abnormal laboratory findings, cancer, history of stroke/myocardial infarction or immunosuppressive therapy.
- The safety and efficacy of the product has not been evaluated in patients treated with other dermal fillers.
- The safety and efficacy of the product after dilution have not been evaluated.
- The safety of HArmonyCa® Lidocaine injectable implant with concomitant dermal therapies such as epilation, UV irradiation or laser, mechanical or chemical peeling procedures has not been evaluated in controlled clinical trials.
- The safety of the product has not been evaluated in diabetic patients.
- HArmonyCa® Lidocaine should not be used in patients under treatment with substances that can prolong bleeding (e.g. aspirin, anticoagulants, thrombolytics, anti-inflammatories, ACE inhibitors) as increased bruising and bleeding may occur.
- HArmonyCa® Lidocaine must not be injected into tissues that may be harmed by the volumising properties of dermal fillers.
- HArmonyCa® Lidocaine must not be injected into or via scar, cartilage, compromised, infected or inflamed tissues.
- Do not over-inject. Over-injection may result in mechanical damage to the tissue.
- Hyaluronic acid is known to be incompatible with quaternary ammonium salts such as benzalkonium chloride. HArmonyCa® Lidocaine should therefore never be placed in contact with these substances or with medical-surgical instrumentation which has been treated with this type of substance.
- There is no known interaction with local anaesthetics other than lidocaine.
- Adverse events associated with the injection of dermal fillers in general and calcium hydroxyapatite-based fillers in particular are often observed, some of which require counselling and treatment by the attending medical practitioner. Refer to the Patient instructions section. Some adverse events may require surgical intervention including drainage of haematomas or seromas and implant removal in cases of severe allergy, inflammation, hypersensitivity or infection.
- Based on preclinical evaluation, patients should be limited to 6.25 mL injectable gel per treatment session, and 20 mL per year, per 60 kg (130 lbs) body mass. The safety of injecting greater amounts has not been established.

- HArmonyCa® Lidocaine gel must be used prior to the expiration date printed on the package.

#### **PRECAUTIONS**

- For use only by authorised healthcare professionals in accordance with local regulation.
- For single use and single patient only. Do not re-sterilise.
- Only the fluid path and syringe content are sterile.
- To be used as supplied. Modification of the product may negatively impact its sterility and performance.
- For use under sterile conditions only.
- Must be used prior to the expiration date printed on the package.
- Do not use if package is open or has been tampered with.
- Do not use if device damage (e.g. cracked or broken syringe barrel, open syringe cap or plunger stopper) is suspected. Discard any damaged devices.
- The healthcare professional must be familiar with the device and implantation procedure and techniques. In using the device, clinical judgment must be made regarding its application. In all cases, sound medical practice is to be followed by the user.
- Use with caution in patients with a history of herpes or recent dental treatments or infection.
- Use with caution in patient currently on immunosuppressive therapy.
- Use with caution when injecting in proximity to other implanted dermal fillers.
- Use with caution when injecting into the marionette lines and oral commissures, do not overcorrect to prevent material migration into the lips.
- Allow at least 4 weeks between ultra-sound based treatments, laser or peeling treatments and use of this product.
- HArmonyCa® Lidocaine injection may be accompanied with mild discomfort; administration of anaesthetics should be considered.
- As a matter of general principle, injection of a medical device is associated with a risk of infection. Standard precautions associated with injectable materials shall be followed.

#### **STORAGE**

- Store between 15°C and 25°C (away from light).
- Avoid prolonged exposure to elevated temperatures.
- Do not freeze.
- Shelf life: 2 years.

#### **PRECAUTIONS FOR USE**

- All used devices must be treated as a potential biohazard. Handle and dispose in accordance with standard medical practices and applicable regulations.
- Carefully inspect all parts for damage. Do not use if any faults are suspected.
- HArmonyCa® Lidocaine is a homogenous gel. Carefully inspect the gel before injection. Do not use if particles, discolouration or signs of separation are visible.
- Patients should be instructed to abstain from use of make-up in the area to be treated for 12 hours before and after the procedure.
- Subsequent treatments may be required to obtain optimal results. Allow for at least seven days between treatments, to enable effective evaluation of the implantation outcome.

#### **Before getting started**

- 1 Prior to treatment, a full patient history should be obtained and the region to be treated should be fully appraised. Patients should be informed of the contraindications, warnings and possible adverse events of treatment.

## Instructions *for Use*

- 2 Assess the patient's need for managing pain and apply, if necessary, the appropriate form of anaesthetic. To reduce local swelling, ice may be applied to the injection site.
- 3 Thoroughly wash the treatment area with soap and water and disinfect with an alcohol swab.
- 4 Extra care should be taken to cleaning and disinfecting patient's skin prior treatment in order to prevent bacterial infection.

### **Attach needle to syringe**

- Suitable disposable sterile 27G (thin-wall) needles are provided. It is advisable to use 25G needles or 27G thin-wall needles in case a needle replacement is needed. Needle occlusion may occur more frequently if smaller diameter needles are used. Larger diameter needles may lead to higher frequency of adverse events caused by skin puncture, such as pain and oedema, and therefore should not be used. For multiple injections, it is recommended to use 27G thin-wall needles.
- Prepare the syringes and injection needles before injection:
  - 1 Remove tip cap - Remove syringe tip cap by holding the luer-lock and screwing the tip cap off as shown in **1**.
  - 2 Insert needle - Hold the syringe body and firmly insert the hub of the needle (provided in the product package) into the Luer-lock end of the syringe.
  - 3 Tighten the needle - Tighten the needle by turning it firmly in a clockwise direction (**2**) until it is seated in the proper position as shown in **3**. If the position of the needle cap is as shown in **4**, it is not attached correctly. Continue to tighten until the needle is seated in the proper position.
  - 4 Remove the needle cap - Hold the syringe body in one hand and the needle cap in the other. Without twisting, pull in opposite directions to remove the needle cap as shown in **5**.
- A new injection needle must be used for each syringe. Never transfer needles between patients.

### **Injecting the gel**

- Different facial regions and severity of volume deficit affect the injection technique and volume of implant injected.
- Stop the procedure immediately if vascular puncture is suspected.
- 1 Insert the needle at an angle of  $-30^{\circ}$  into the deep dermis. The bevel should be oriented downwards to minimise implant deposition into a more superficial plane. Palpate the region with your free hand to confirm insertion of the needle into the skin layer of interest.
  - Superficial injection or deposition of large volumes of the implant may result in discolouration, nodules or ischaemia at the skin surface.
  - Avoid injecting into or via scar and cartilage tissues.
  - Verify (e.g. by aspiration before injection) that you are not injecting the implant into a blood vessel.
- 2 Inject the gel by applying mild continuous pressure on the plunger rod, while slowly withdrawing the needle, thus forming a single uniform thread of injected gel inside the tissue (linear threading technique). When correcting deep folds, several threads should be layered in parallel lines beneath the fold. If larger volumes are required, such layers can be deposited on top of each other, the threads of each layer are perpendicular to those in the underlying layer (cross hatching technique).
- 3 Substantial mechanical resistance to the injection of the implant may be resolved using the following measures: First, horizontally relocate the needle; second, inject from a different entry point; third, replace the needle or even the syringe.
- 4 Blanching may indicate injection into a superficial skin layer or into a blood vessel. In case of blanching, stop injecting and massage the area until colour returns to normal.

- 5 If normal skin colour does not return, the injection process should not be resumed and vasodilatory or other measures should be considered.
- 6 Stop injection before pulling the needle out of the skin to avoid gel leakage into superficial skin layers.
- 7 Do not overcorrect.
- 8 Discard needle in appropriate biohazard waste bin.
- 9 Repeat the procedure if further correction is necessary but only after thoroughly assessing the treated area and patient status.
- 10 After completing the injection, gently massage the treated area to ensure even distribution of the gel and to mould the gel to the tissue contour.
- 11 If overcorrection has occurred, firmly massage the area to obtain optimal results.

#### Patient instructions

The following information should be shared with the patient:

- 1 Patient should avoid strenuous activity and exposure to sunlight and tanning lamps or extreme weather conditions for 24 hours post-treatment in order to reduce redness, swelling and irritation.
- 2 Patient should apply an ice pack or cold compresses to the treated area for 24 hours post-treatment in order to reduce redness, swelling and irritation.
- 3 If nodules appear, patient should massage the treated area.
- 4 Patient should be informed that the injected material may be palpable for a long period after treatment.
- 5 The most common side effects include temporary reactions at the treatment site such as erythema, oedema, itching sensation, bruising, pain, tenderness to touch, nodules, local reaction or inflammation at the injection site. These side effects are consistent with other injectable soft tissue fillers.
- 6 Less common side effects include granulomas, seroma, extrusion, induration and fistula formation.
- 7 Other side effects such as haematoma, skin discolouration, allergic reaction, migration, infection, unintentional injection into a blood vessel may lead to vascular occlusion, embolisation, vision abnormalities, blindness, stroke or skin necrosis.
- 8 Although most common side effects will resolve within 1 week, some side effects may last for 30 days or longer. If unresolved, the healthcare practitioner should use appropriate treatment.
- 9 Adverse events are reported following the use of soft tissue fillers, including hyaluronic acid fillers with or without calcium hydroxyapatite. Some of these events necessitate counselling and management by the healthcare provider. In certain instances, surgical interventions may be required, such as draining haematomas or necrotic tissue, or removing the implant due to severe allergic reactions, inflammation, hypersensitivity or infection.
- 10 Patients should be asked to promptly report the following to the medical practitioner about:
  - any common adverse event which doesn't resolve within the typical time frame or which worsens.
  - any other adverse event.






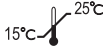










HArmonyCa<sup>®</sup> Lidocaine contains trace amounts (<2ppm) of the cross linking agent butanediol diglycidyl ether (BDDE).

#### POISON SCHEDULES

S4 in all Australian states.

Allergan Aesthetics

## Instructions for Use

 Do not use if package is damaged and consult instructions for use.	 Do not re-sterilize	 Do not re-use	 Manufacturing Date YYYY/MM/DD	 Batch code
 Temperature limit	 Consult instructions for use or electronic instructions for use	 Prescription device	 Use by Date YYYY/MM	 Catalogue number
				
 <b>Manufactured by:</b> Panaxia LTD 13 Hamelacha St. Lod, 7152026, Israel Tel: +972 72 2744141		 <b>Manufactured by:</b> TSK Laboratory, Japan 1510-1 Soja-Machi Tochigi-Shi, Tochigi-Ken 328-0002-Japan		
 Filled Syringe - Sterile fluid path (Sterilised using steam)		 Needle (Sterilised using irradiation)		

### Manufacturer:

Panaxia LTD  
13 Hamelacha St., Lod  
7152026, Israel  
Tel: +972 72 2744141

### Australian distributor:

AbbVie Pty Ltd  
Mascot NSW 2020  
Australia

### New Zealand distributor:

AbbVie Limited  
Wellington 6011  
New Zealand



Allergan Aesthetics



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20089383  
Revision 2025-09-17

2 Patient Implant  
Cards  
to be provided to patients  
injected with  
**HArmonyCa<sup>®</sup>**  
**Lidocaine**  
are being provided.

Please ensure you add the  
Batch/Lot number to the  
Patient Implant Card prior to  
providing it to the patient.

Please note that additional  
space has also been provided  
on the reverse of the Patient  
Implant Card for you to insert  
the name of the injecting  
doctor and/or treatment clinic.

**HArmonyCa<sup>®</sup>**  
Lidocaine



Refer to Patient Information Leaflet:



[www.allerganaesthetics.com.au/our-products/harmonyca](http://www.allerganaesthetics.com.au/our-products/harmonyca)  
or <http://www.allerganaesthetics.co.nz/>

**Manufacturer:**  
Panaxia LTD  
13 Hamelacha St.,  
Lod, 7152026 Israel

**Australian Distributor:**  
Abbvie Pty Ltd  
Tel (AU): 1800 252 224  
Tel (NZ): 0800 659 912

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Lidocaine



Refer to Patient Information Leaflet:



[www.allerganaesthetics.com.au/our-products/harmonyca](http://www.allerganaesthetics.com.au/our-products/harmonyca)  
or <http://www.allerganaesthetics.co.nz/>

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